

Structure, Function, Validation and Integration of Automated 96 Well Plate Processing System with Hamilton StarLet Liquid Handling Station

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INTRODUCTION & OVERVIEW

- 96 Well-plate processing system is a customized program and provides an interface between LIMS systems (such as ALIS-2004, Watson, Nautilus, etc.) and automated liquid handling systems (Hamilton StarLet, Perkin Elmer MultiProbe, Tecan Freedom EVO, Caliper Sciclone, etc.).
- ALIS-2004 and 96 well plate processing system stores all information, including audit trails and encrypted electronic signatures in a secure database.
- The 96 well plate processing module provides bi-direction interface to communicate with Hamilton's StarLet liquid handling system.
- A run list containing the sample location, sample characteristics and barcode is produced by the plate processing system. Hamilton Starlet reads the sample barcode and verifies the final plate position specified in runlist.
- Validation of plate processing system incorporates functional and design specifications, and user test scripts; in addition to IQ, OQ and PQ.
- The 96 well plate processing system integrated with Hamilton StarLet enables laboratory staff in tracking and managing sample preparation processing information electronically complete with audit trails.
- Use of a 96 well plate processing system with Hamilton StarLet allows full automation of instrument runlist generation for Sciex API 3000/4000/5000 instruments.

SYSTEM DESIGN & COMPLIANCE CONSIDERATION

The key GLP requirements that were taken into consideration during the design phase of the project are shown in the Figure 1 and 2 below. The 96 well plate processing solution was built using readily available off-the-shelf components from Microsoft. The software program was written using MS Visual Studio, Access database and Crystal Reports.

System Design Considerations	
GLP/Part 11 Requirement	Feature Description
Electronic Signature	Log-In Module (User ID and Password Management)
Audit Trail (Date-Time Stamp)	Audit Module (Record Preservation & Encrypted Esig)
Restricted User Access & Rights	Plate Processing Module
Plate Template Builder	Sample Type Assignment (QCs, Standards, Samples,...)
Run List and Bar-coded Labels	Sample's Plate Position and customized barcodes
System Validation	Validation Test Scripts: DQ/IQ/OQ/PQ

Figure 1

System Components	
Software	Hardware
MS Windows 2000/XP	Pentium 4 PC, 1 GB RAM, 80 GB drive, 100/1000 MB ethernet
MS Visual Studio	100/1000 MB Ethernet
MS Access	Hamilton StarLet Liquid Handling System
MS Excel	
Business Object's Crystal Reports	
Hamilton StarLet Vector Software	

Figure 2

STRUCTURE OF A 96 WELL PLATE PROCESSING SYSTEM

- 96 Well-plate processing system consists of a several modules, customized user interface for data entry and tables to store all information related to a plate.
- The data repository contained in database tables can be queried to produce predefined as well as customized reports.
- The runlist file is produced as a MS-Excel format file containing the sample locations, sample types (QCs, Standards, Sample,...), aliquot, etc.
- The system generates barcoded sample labels for location verification by Hamilton StarLet.
- A plate template builder utility allows production and customization of plate map based on various sample types.

FEATURES & FUNCTIONALITY OF 96 WELL PLATE PROCESSING SYSTEM

Plate Template Builder

- Allows a method specific plate template map to be built by assigning sample types (QCs, AQL, SA, ST, EE, BT, FT, etc) to various rows and columns of a 12x8 plate map.
- Assignment of a unique Plate Map ID.
- Rapid and efficient duplication (cloning) and modification of an existing plate map to meet method specific criteria.
- Assignment of a single plate map to multiple plates.

Plate Processing

- Allows assignment of plate map to a plate.
- Assignment of a unique Plate ID, and multiple plates (Plate IDs) per Prep. Batch.
- Multiple views of a plate based on "Sample Type" or "Sample ID" for efficient data access and processing.
- Fail safe feature preventing samples from getting deleted or modified upon loading on a processed plate.

Plate Sample Loader

- Provision for loading "All" Sample IDs or specified range of Sample IDs based on "Sample Type" on a plate.
- Sample Type and Sample ID verification to flag incorrect and mismatched samples prior to loading on a plate.

Plate Run List

- Allows selection of runlist output types - Hamilton StarLet or TomTec Quadra.
- Run list output formatted and saved as MS-Excel file in a secured and restricted access folder.
- Provision for versioning of Run List files.

Plate Reports & Plate Barcoded Sample List

- Plate report output to a printer or a user definable file format (MS-Excel, MS-Word, TXT, etc).
- Plate's Sample Location and Sample ID, QC Type, Aliquot Factor, Dilution Factor etc., in a Code 39 or Code 128 formatted barcode.

INTEGRATION OF 96 WELL PLATE PROCESSING WITH HAMILTON StarLet's VECTOR DATA SYSTEM

- Plate map is generated in Plate Processing System specifying the final location of each sample
- A sample runlist and bar coded sample labels are produced by Plate Processing System according to the plate map.
- Samples are loaded onto the StarLet deck according to the deck layout map (Figure 4).
- The runlist is then read by Starlet, which contains the final location for each sample.
- Starlet Vector software reads the sample barcode, then matches it to the final plate position specified by Plate Processing System for verification and appends to the runlist.
- Each sample is aliquotted onto the extraction plate according to the run list.
- The barcode of the sample can be matched to the final destination of the sample in extraction plate.
- The StarLet plate extraction/aliquot method is transferred to ALIS-2004's project folder (Figure 3).
- The plate runlist containing the vial and rack positions is then utilized to upload samples for analysis by Sciex API instrument using Analyst 1.40 SP6 (Figure 3).

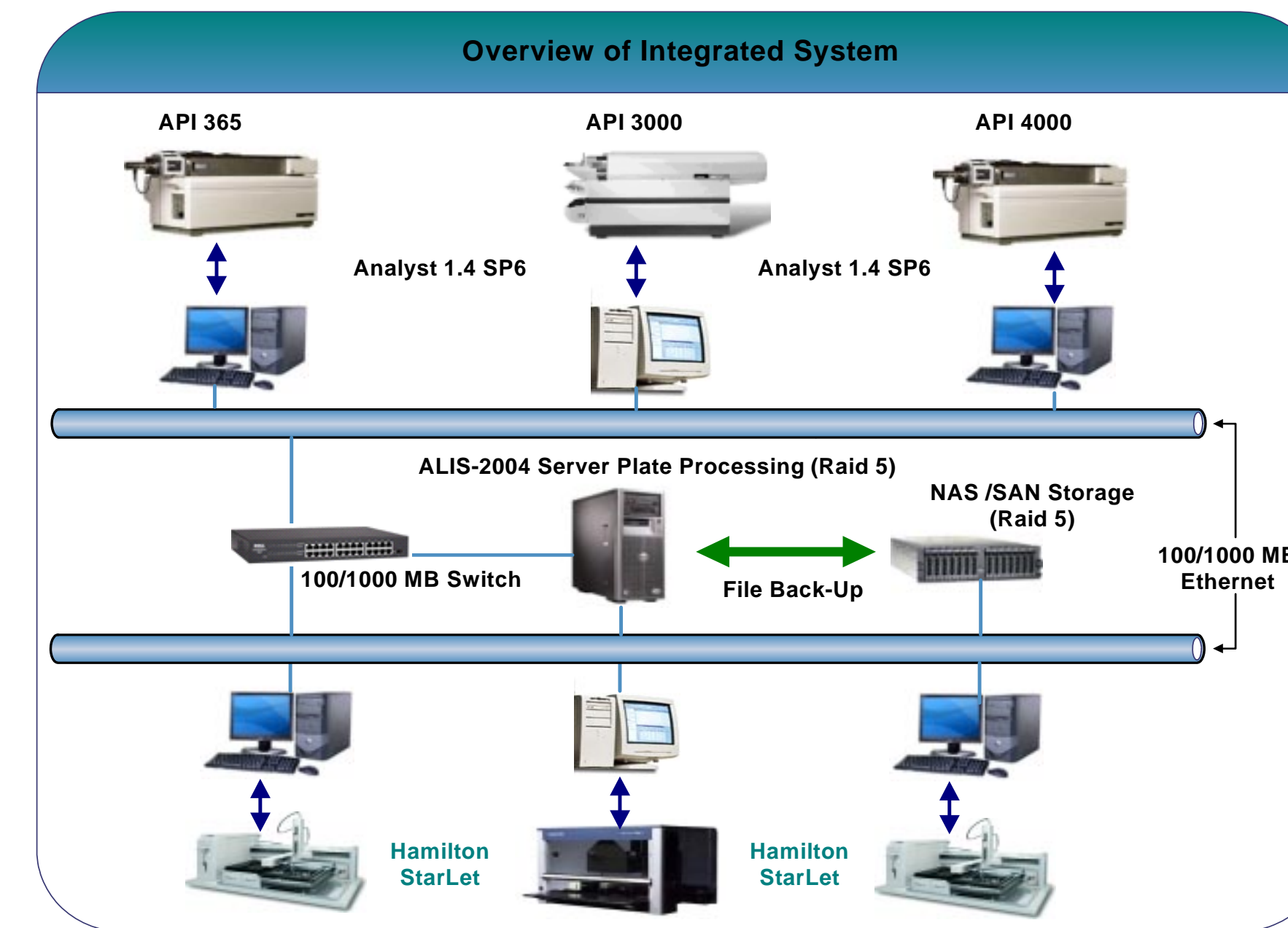


Figure 3

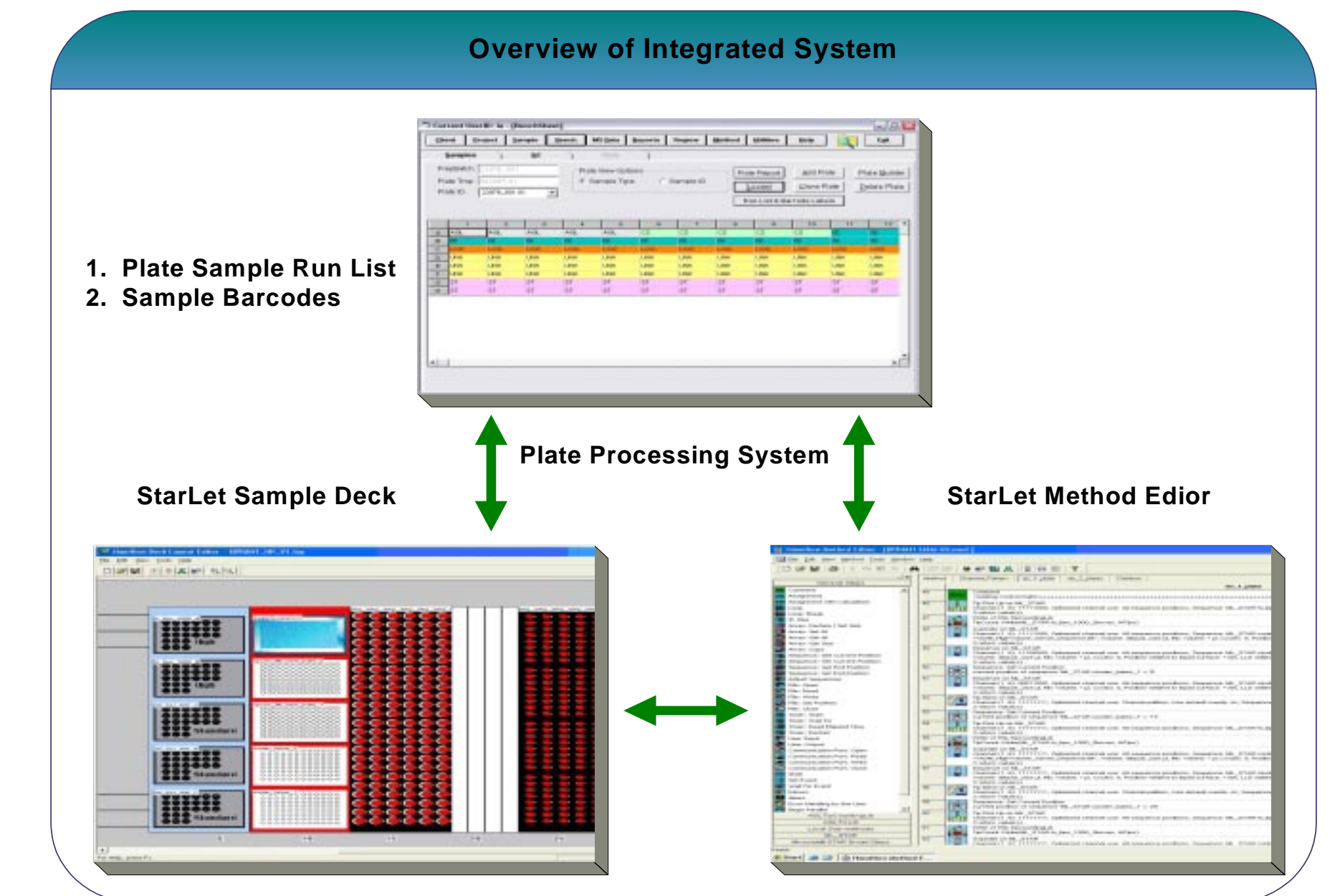


Figure 4

96 WELL PLATE PROCESSING SYSTEM VALIDATION STUDY

The program consists of four main modules; Plate Processing (main screen), Plate Template Builder, Plate Runlist, Plate Reports and Barcoded labels. The functional design of the program was defined by user requirements (organized by module). The Validation Test Plan provided a test matrix that correlated each user requirement with a test script sequence. The Validation Study was performed by the compliance specialist who relied on the user manual and training provided by the in-house IT group. In addition to the software Validation Study, an IQ, OQ and PQ were completed to document system installation and performance (Figures 5 and 6).

Validation Components

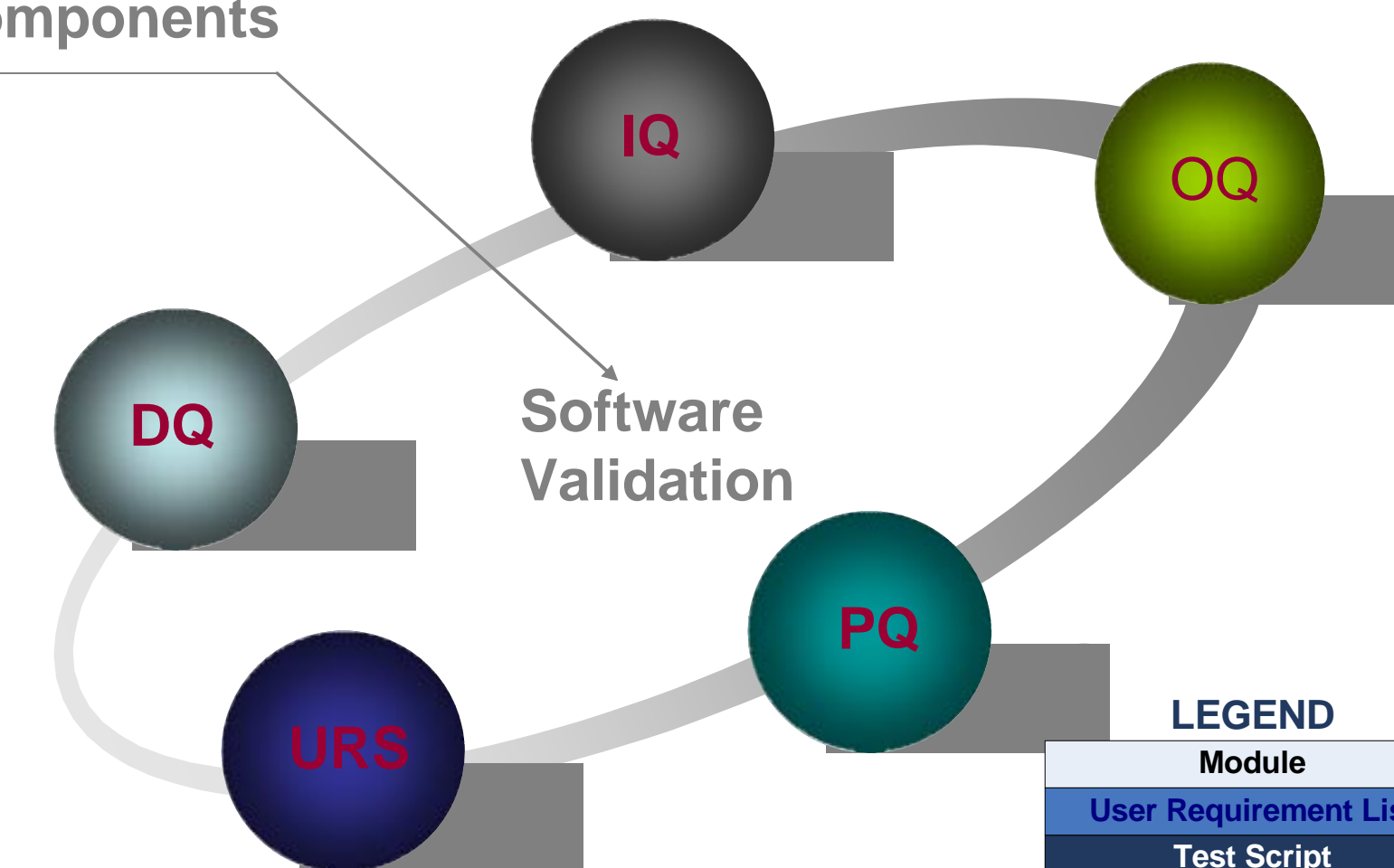


Figure 5

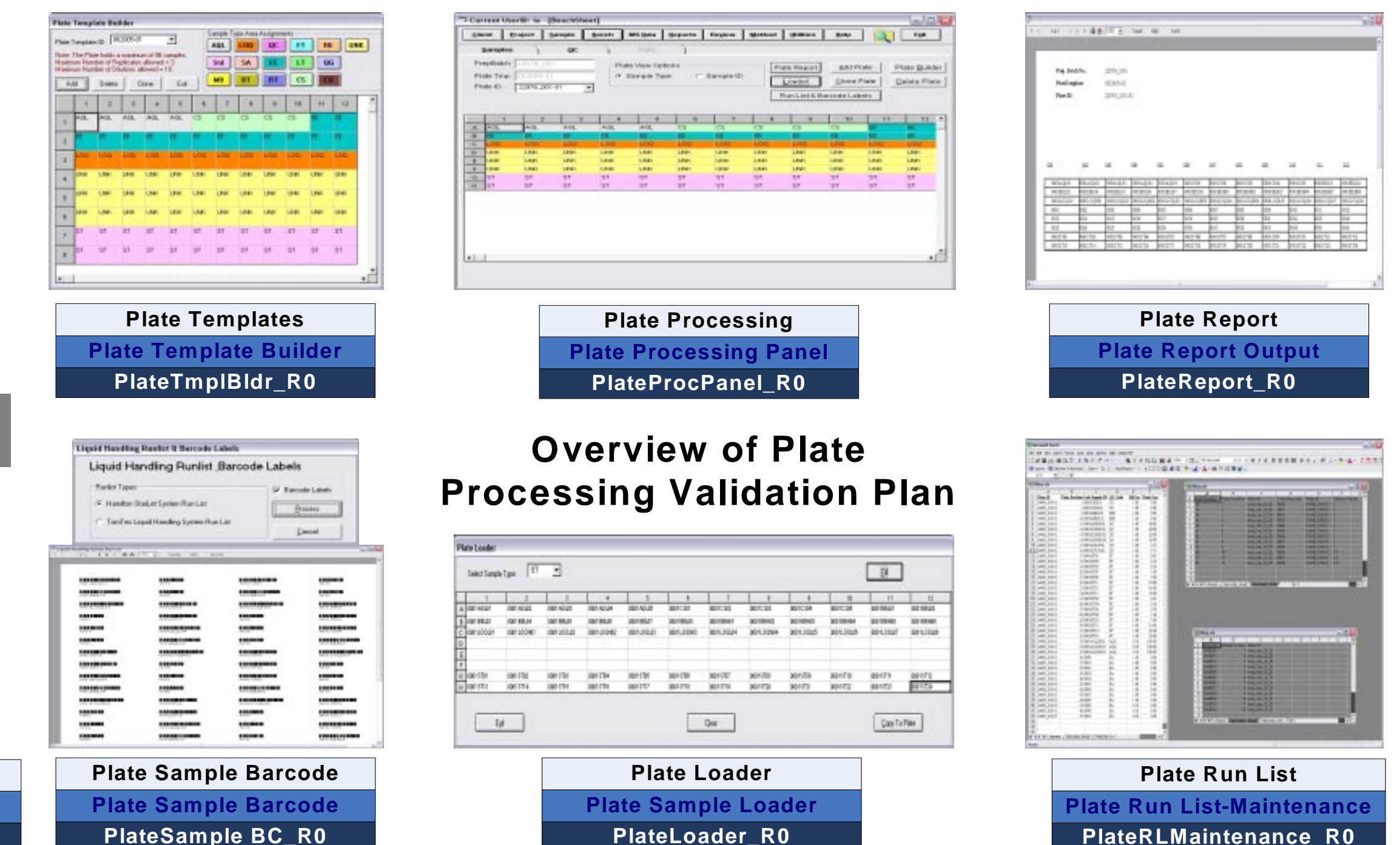


Figure 6